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FOOD AND DRUG ADMINISTRATION  
DIETARY SUPPLEMENT STAKEHOLDER MEETING  
OAKLAND FEDERAL BUILDING  
1300 CLAY STREET  
OAKLAND CALIFORNIA

PANEL III (HEALTH PROFESSIONALS/ORGANIZATIONS; ACADEMIA):  
R. LAWRENCE SULLIVAN, JR., M.D.  
AMERICAN SOCIETY OF ANESTHESIOLOGISTS

My name is Dr. Larry Sullivan, and I am here today on behalf of the American Society of Anesthesiologists, a scientific and educational organization that represents more than 35,000 physicians across the United States, and which is dedicated to patient safety and quality medical care. My purpose is to urge the Food and Drug Administration to take immediate and appropriate action that will provide safer and more predictable herbal medications to the public, and hopefully remove much of the mystery associated with these potent products.

As a physician who has practiced anesthesiology for nearly twenty-five years, I will make no claim to being an authority on herbal remedies. It is well known, however, that many of the medications commonly used by physicians such as cardiac drugs, analgesics, and antibiotics had their origin in botanicals, molds, or other natural substances. As the science and the practice of medicine have grown, the controlled study of thousands of useful medications over the past century has helped to define the safety, usefulness, and appropriate indications for these drugs, the result of which has been the successful and safe pharmacologic treatment of many diseases. Within this framework, the FDA has effectively established standards for quality and safety for such medications.

Unfortunately, the expectations in the use of herbal medications is unclear. I am aware that the availability and the use of unregulated herbal preparations have increased dramatically over the last few years. Physicians, who once learned in medical school about digitalis, morphine, penicillin, and epinephrine, now are faced with the likes of ginseng, ephedra, ginkgo, and St. John's Wort. As an anesthesiologist, I care for patients before, during, and after surgery. No surgery should ever proceed until the anesthesiologist determines that the patient is well enough to survive all of the risks associated with the anesthesia and the procedure. But anesthesiologists are troubled by the fact that as many as 70% of patients do not tell their physicians that they are taking herbal medications because they mistakenly view these products as completely safe. Because many of these products can have a profound effect on a patient's physiology, problems such as unstable blood pressure, cardiac arrhythmias, prolonged anesthesia, and

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even disrupted clotting function can occur. This adversely impacts the well-being and safety of a patient in a surgical setting.

Although many herbal products are innocuous, some are not. There have been anecdotal reports by members of the American Society of Anesthesiologists that suggest that, in patients taking various herbal medications, untoward and unexpected reactions to anesthetics may occur. For instance, the presence of ephedra, used in many diet preparations, either alone or mixed with other ingredients, may contribute to unexpected arrhythmias or hypertension under anesthesia. The use of St. John's Wort, sometimes recommended for depression or anxiety, may prolong anesthesia or negatively interact with other antidepressants such as monoamine oxidase inhibitors, thus precipitating erratic blood pressure changes. Patients consuming ginkgo biloba may be subject to bleeding problems due to platelet inhibition. Likewise, the popular preparation for migraine prophylaxis, called feverfew, can also interfere with proper clotting function.

The dilemma that anesthesiologists face is not only that patients are taking pharmacologically active herbal preparations that their physician may be unaware of, but little is known about the actual potency and preparation of these substances. In addition, the lack of valid scientific information on the interactions of these substances with many prescription type drugs also poses a potential threat to patients receiving an anesthetic.

The ASA strongly urges the FDA to establish a database or other reporting system where data on adverse events can be analyzed, with a particular focus on adverse reactions with anesthetics or in a surgical setting. Additionally, the FDA should be charged with establishing minimum standards of production, quality, safety, potency, and labeling. It should likewise be the responsibility of manufacturers to ensure the safety and efficacy of these herbal remedies by complying with such standards. Only then can meaningful research on drug interactions be achieved. Finally, it is essential that physicians become more aware of the potential hazards of herbal or "natural" remedies, especially when used concurrently with prescription medications or with anesthetics. It is equally important that patients be educated as to these potential hazards and especially be aware of the need to inform their physician of their use.